



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA-2016-D-4120]

Fruit Juice and Vegetable Juice as Color Additives in Food; Draft Guidance for Industry; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the notice entitled "Fruit Juice and Vegetable Juice as Color Additives in Food; Draft Guidance for Industry" that appeared in the *Federal Register* of December 14, 2016. The draft guidance, when finalized, will help manufacturers determine whether a color additive derived from a plant material meets the specifications under certain FDA color additive regulations. We are taking this action in response to requests to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the proposed rule published December 14, 2016 (81 FR 90267). Submit either electronic or written comments by **[INSERT DATE 60**

DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including

attachments, to <https://www.regulations.gov> will be posted to the docket unchanged.

Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-4120 for "Fruit Juice and Vegetable Juice as Color Additives in Food; Draft Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." We will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Laura A. Dye, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1275.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of December 14, 2016 (81 FR 90267), we published a notice of availability of a draft guidance for industry entitled "Fruit Juice and Vegetable Juice as Color Additives in Food." The draft guidance, when finalized, will help manufacturers determine whether a color additive derived from a plant material meets the specifications for fruit juice under § 73.250 (21 CFR 73.250) or vegetable juice under § 73.260 (21 CFR 73.260). Although you can comment on any guidance at any time, to ensure that we consider comments on this draft guidance before we begin work on the final version, interested persons were originally given until February 13, 2017, to comment on the draft guidance.

We have received requests to extend the comment period for the draft guidance. The requests conveyed concern that the original 60-day comment period would not allow sufficient time to develop a meaningful or thoughtful response to various issues presented in the draft guidance and to our interpretation of our regulations. We have considered the requests but were unable to issue a document extending the comment period for the draft guidance before February 13, 2017. Consequently, we are reopening the comment period for an additional 60 days.

Interested parties have until **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**. We believe that this action allows adequate time for interested persons to submit comments on the draft guidance without significantly delaying finalizing the guidance.

Dated: February 23, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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